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I	APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
۰	10/728,246	12/04/2003	Cindy Orser	ADL-101	8108	
	59241 LATIMER IP I	7590 04/05/2007 LAW, LLP		EXAMINER	INER	
	13873 PARK C	CENTER ROAD		MOSS, KERI A		
	SUITE 122 HERNDON, V	TE 122 RNDON, VA 20171		ART UNIT	PAPER NUMBER	
,				1743	1743	
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l	SHORTENED STATUTOR	RY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
_	3 MO	ONTHS	04/05/2007	PAI	PER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

		Application No.	Applicant(s)				
		10/728,246	ORSER ET AL.				
	Office Action Summary	Examiner	Art Unit				
		Keri A. Moss	1743				
Period fo	The MAILING DATE of this communication or Reply	appears on the cover sheet with the	correspondence address				
A SHO WHIC - Exter after - If NO - Failu Any r	ORTENED STATUTORY PERIOD FOR RECHEVER IS LONGER, FROM THE MAILING asions of time may be available under the provisions of 37 CF SIX (6) MONTHS from the mailing date of this communication period for reply is specified above, the maximum statutory per to reply within the set or extended period for reply will, by steply received by the Office later than three months after the med patent term adjustment. See 37 CFR 1.704(b).	G DATE OF THIS COMMUNICATIO R 1.136(a). In no event, however, may a reply be tint.  In this individual serior of the communication of t	N. mely filed the mailing date of this communication. ED (35 U.S.C. § 133).				
Status							
1)	Responsive to communication(s) filed on <u>09 February 2007</u> .						
•		This action is non-final.					
3)	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Dispositi	on of Claims						
4)🖂	4)⊠ Claim(s) <u>105-145</u> is/are pending in the application.						
	4a) Of the above claim(s) is/are withdrawn from consideration.						
5)	5) Claim(s) is/are allowed.						
6)🛛	6)⊠ Claim(s) <u>105-145</u> is/are rejected.						
• —	7) Claim(s) is/are objected to.						
8)□	Claim(s) are subject to restriction ar	nd/or election requirement.					
Applicati	on Papers						
9) The specification is objected to by the Examiner.							
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11)	11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority u	ınder 35 U.S.C. § 119						
	<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> </ul>						
	2. Certified copies of the priority docum	nents have been received in Applicat	tion No				
	3. Copies of the certified copies of the application from the International Bu		ed in this National Stage				
* 8	See the attached detailed Office action for a	list of the certified copies not receiv	ed.				
Attachment(s)  1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)							
2) Notic	2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date.						
3) 🛛 Infor	mation Disclosure Statement(s) (PTO/SB/08)  or No(s)/Mail Date <u>See Continuation Sheet</u> .	5) Notice of Informal 6) Other:	Patent Application				
	S. Patent and Trademark Office						

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## DETAILED ACTION

Applicant's response to Election Restriction Requirement is hereby acknowledged. As is Applicant's included cancellation of claims 1-104.

Claims 105-145 are pending.

## Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 2. Claims 105-145 are rejected under 35 U.S.C. 102(e) as being anticipated by Krishnamurthy (US 6,399,314).

Krishnamurthy teaches detection of aggregated forms of amyloid peptide using amyloid-specific spectroscopic probes. As a control test, Krishnamurthy teaches combining the amyloid-specific spectroscopic probe with amyloid polypeptide under conditions which permit aggregation (column 2, lines 51-59). In column 6, line 33, et seq., Krishnamurthy defines "amyloid-specific spectroscopic probe to include a peptide-fluorophore conjugate that interacts with aggregated forms of amyloid. Krishnamurthy goes on to state that "fluorophore-labeled amyloid peptide," which presumably is the peptide-fluorophore conjugate discussed above, can be portions of amyloid

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polypeptides capable of co-aggregating with amyloid polypeptides, but not necessarily capable of aggregation on their own. This appears to be equivalent to applicant's independent claim where a fluorophore-labeled amyloid peptide is the probe which is added to a specimen containing abnormal proteinaceous particles (amyloid polypeptide). In column 7, line 30, et seq., Krishnamurthy also discusses that the aggregation complex is formed between the amyloid-specific spectroscopic probe with aggregated amyloid polypeptide by co-aggregating the probe with the polypeptide by having the probe present with the polypeptide prior to induction of aggregation. This appears to be identical to applicant's claim recitation where the probe undergoes a conformational change which results in an increase in beta-sheet structure. Krishnamurthy detects differences in spectroscopic properties, such as strength of fluorescence. It would appear that the strength of the fluorescence is related to the amount of fluorophore in the co-aggregate, which would be a detection of the increase in formation of beta-sheet structure. In columns 1-2, Krishnamurthy teaches that misfolded proteins are known to cause Alzheimer's Disease

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## Double Patenting

3. Claims 105 and 125 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,166,471.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the only apparent difference between the claims is the naming of the probe, which is called a peptide probe in the instant application and is called a

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propagation catalyst in the '471 patent. The mechanism of action between the probe and the propagation catalyst are the same as they both exhibit a random coil alpha-helix conformation in solution and both undergo a conformational shift upon contact with a misfolded protein. This action is how a misfolded protein is detected in both the instant application and the '471 patent.

## Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keri A. Moss whose telephone number is 571-272-8267. The examiner can normally be reached on 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jill Warden
Supervisory Patent Examiner
Technology Center 1700

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Keri A. Moss Examiner Art Unit 1743

KAM 4/2/2007

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :2/2/04;8/16/04;1/24/05;10/28/05;1/3/07.